2. Non-Technical Abstract

This is a study evaluating the safety and feasibility of treating patients with bladder cancer by placing a vaccine into their bladders. This will be done with the hope of creating an immune reaction against the bladder cancer. Patients with bladder cancer that has invaded (spread) into the muscle layer of the bladder and have chosen to have their bladder surgically removed as a standard treatment for their cancer stage, will be eligible for treatment on this study. Removal of the bladder is not a curative procedure for all patients and there is still potential of recurrence. Hence, there is a need for exploring other treatment options to improve upon these results. Therefore, we are proposing a study that tests the possibility of vaccinating against any remaining bladder tumor that the patient may have by placing a vaccine into the bladder prior to its removal. Vaccination will be done once per week for four consecutive weeks prior to surgery. The last vaccination will be given 48-96 hours before surgery. It is hoped that the immune reaction against the bladder cancer. if created with this type of vaccination. may lead to an improved cure rate for these patients. This study is designed to demonstrate the feasibility and safety of such vaccination and to determine how the immune system responds to the vaccine placed into the bladder. The vaccine will consist of an altered fowlpox virus that carries the gene for a single immune stimulating protein (GM-CSF or TRICOM) or a combination of the two viruses. When placed into the bladder, the virus will infect bladder cells and remaining tumor and cause them to make the immune-stimulating agent(s). These agents have been shown in laboratory and patient studies to improve immunity against tumors and increase the potency of other vaccines. Patients will be alternately assigned to the GMCSF or TRICOM single agent treatment groups. Following the completion of the single agent groups and having demonstrated the safety of each agent. patients will be assigned to the combination group. This will help us to determine what degree of immune reaction each of the vaccine and the combination produces. This information will help us to develop the next clinical trial measuring the effects of this type of vaccine against bladder tumor. There will be a total of between 24 and 42 patients treated in this study.